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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/055,711

01/22/2002

Edward Rebar

8325-0025

6236

20855

7590

12/23/2005

ROBINS & PASTERNAK
1731 EMBARCADERO ROAD
SUITE 230
PALO ALTO, CA 94303

EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/055,711

Applicant(s)

REBAR ET AL.

Examiner

Jennifer Dunston

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1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 December 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 2, 4, 6, 10, 22, 25-28, 30-32, 36, 37, 39-41 and 53.
Claim(s) withdrawn from consideration: 1, 3, 5, 7-9, 11-21, 23, 24, 33-35, 38 and 42-52.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See the continuation sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 12/7/2005
13. ☐ Other: _____

CONTINUATION SHEET

Information Disclosure Statement

Receipt of an information disclosure statement, filed on 12/7/2005, is acknowledged.

The signed and initialed PTO 1449 has been mailed with this action.

Election/Restrictions

This application contains claims 1, 3, 5, 7-9, 11-21, 23-24, 33-35, 38 and 42-52 drawn to an invention nonelected with traverse in papers filed 8/3/2004 and 11/18/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant asserts that claims 3, 5, 7-9, 11-21, 23, 24, 34, 35 and 38 will be considered upon allowance of generic claim 30. The assertion that claim 30 is a generic claim is incorrect. Claim 30 is drawn to a polynucleotide, which falls within elected Group II. Group I is drawn to an isolated protein, and Group III is drawn to a method of using the polynucleotide of Group II and does not use the protein of Group I as claimed.

In the Office action mailed 7/1/2004, the examiner required restriction between product (elected Group II) and process claims (non-elected Group III). Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a**

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matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with the 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Response to Arguments – 35 USC § 112 (written description)

Applicant's arguments filed 12/7/2005 have been fully considered but they are not persuasive.

The response asserts that the specification as filed provides literal description of every possible representative species of the claimed invention (response, page 3). The response points to page 4, lines 6-14; page 7, line 19 to page 8, line 5; and page 19, line 14 to page 20, line 15 for support. At page 4, lines 6-14, the specification sets forth primary structures in the form of amino acid consensus sequences, wherein the amino acids that normally coordinate the zinc atoms (e.g. C₂H₂) have been altered. The formulas essentially represent zinc fingers of BCH₂, CBH₂, C₂ZH, C₂HZ, BBH₂, BCZH, BCHZ, CBZH, CBHZ, C₂ZZ, CBZZ, BCZZ, BBHZ, BBZH, and BBZZ, wherein B is any amino acid except cysteine and Z is any amino acid except histidine. The information provided by the primary amino acid sequences does not provide any structural information with regard to the ability of the primary sequence of the protein to form the claimed secondary structures. Further, the primary sequence does not provide any functional information with regard to the ability of the protein to bind a target sequence. At page 7, line 19 to page 8, line 5, the primary sequences referred to above are reiterated. At page 19, line 14 to page 20, line 15, the specification sets forth primary structures in the form of amino acid consensus sequences, wherein the amino acids that normally coordinate the zinc atoms (e.g. C₂H₂) have been altered. The formulas essentially represent zinc fingers of YCHY, CYHY, CYHY, CCYY, CYYY, YCYY, YYHY, YYYY, and YYYY, wherein Y is any amino acid except histidine or cysteine. Once again, the information provided by the primary amino acid sequences does not provide any structural information with regard to the ability of the primary

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sequence of the protein to form the claimed secondary structures. Further, the primary sequence does not provide any functional information with regard to the ability of the protein to bind a target sequence. The response that based upon the description of the primary amino acid sequences set forth in the specification, the skilled artisan would know which amino acids could be at each residue of the claimed molecule and would be aware that Applicants were in possession of every molecule of the claimed genus (response, page 3). This is not found persuasive. Although the skilled artisan could envision every possible sequence substitution in each of the consensus sequences provided in the specification, one would not be able to determine the ability of the sequence to coordinate zinc atoms, form the claimed secondary structure or perform the claimed function of binding to a target sequence.

The response asserts that the Examiner appears to be requiring Applicants to list out particular amino acid residues in each position (X, B, Z and/or Y) of the molecule recited in the claims (response, page 3). This is not necessary, as one of skill in the art could envision every single amino acid change to the primary amino acid sequence represented by the formulas within the specification and claims. Further, the response asserts that a skilled artisan could readily choose any of the nineteen known amino acids excluding cysteine for B, any of the nineteen known amino acids excluding histidine for Z, any of the eighteen amino acids excluding histidine and cysteine for Y, and thus a skilled artisan could make the amino acid replacements (response, page 4). The response asserts that these substitutions meet the written description requirement (response, pages 3-4). For adequate written description and evidence of possession of the claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus such as a complete or partial structure in the form of a primary amino

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acid sequence capable of forming the claimed secondary structure and performing the claimed function. The specification does not provide a correlation between the described primary amino acid sequence and the ability to form the claimed secondary structure commensurate in scope with the claims. Further, the specification does not provide a correlation between the described primary amino acid sequence and claimed function commensurate in scope with the claims. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision a representative number of polynucleotides that satisfy the structural and functional limitations of the claims.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, <http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC)

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for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston
Examiner
Art Unit 1636

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CELIAN QIAN
PATENT EXAMINER

